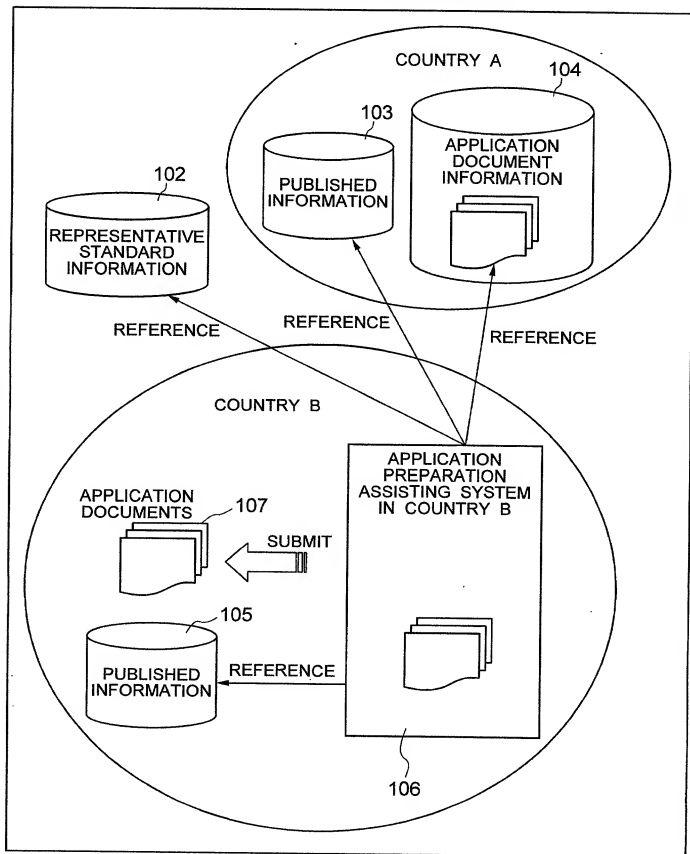


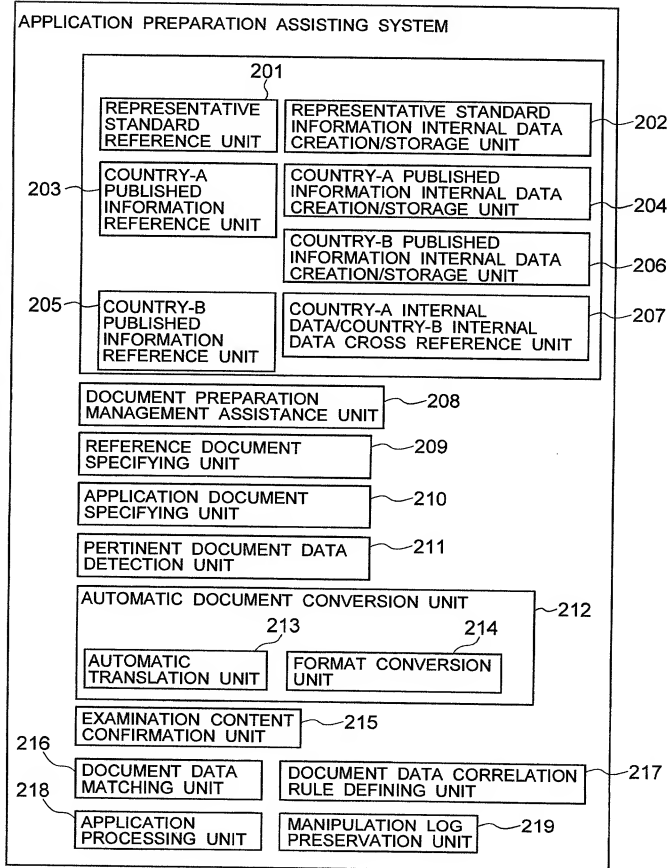
1/11

## FIG. 1

GENERAL CONFIGURATION OF APPLICATION  
PREPARATION ASSISTING SYSTEM

206120-15592001

FIG. 2

CONFIGURATION OF APPLICATION PREPARATION  
ASSISTING SYSTEM

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## FIG. 3

EXAMPLE OF REFERENCE DOCUMENT  
SPECIFYING SCREEN

301

### EXAMPLE OF REFERENCE DOCUMENT SPECIFYING SCREEN

☐ NEW PREPARATION

☒ SELECT AN APPLICATION FOR REFERENCE FROM THE  
FOLLOWINGS WHEN ALREADY PERMITTED.

PERMITTING  
COUNTRY

COUNTRY A



302

PRODUCT  
NAME

GASTROINTESTINAL DRUG ALPHA

303

OTHER SEARCH KEYWORD

304



DOCUMENTS FOUND BY SEARCH : 305

✓ DOCUMENT No. XXX ON GASTROINTESTINAL 306  
DRUG ALPHA PERMITTED IN COUNTRY A

OK

CANCEL

10076554-021400

FIG. 4

EXAMPLE OF SCREEN FOR CONVERTING REFERENCE  
DOCUMENT TO DOCUMENT CONFORMING TO COUNTRY  
TO BE APPLIED

400

SCREEN FOR SPECIFYING CONVERSION TO COUNTRY OF INTEREST

SELECT COUNTRY TO WHICH NEW APPLICATION IS  
MADE, AND APPLICATION METHOD

COUNTRY TO  
BE APPLIED

COUNTRY B



401

USE

COMMERCIALLY  
AVAILABLE DRUG



402

SHAPE OF  
DRUG

CAPSULE



403

COMPONENT

WITHOUT  
ADJUSTMENT



404



405

WITHIN DOCUMENTS REQUIRED FOR APPLICATION,  
DATA EXISTS CORRESPONDING TO DOCUMENTS  
MARKED WITH SHADED SQUARE.  
DO YOU SELECT AUTOMATIC CONVERSION ?

406



APPLICATION 1



APPLICATION 2



APPLICATION 3



APPLICATION 4



APPLICATION 5



APPLICATION 6



APPLICATION 7



APPLICATION 8



APPLICATION 9

407

AUTOMATIC  
CONVERSION

EDIT  
DOCUMENT

408

## FIG. 5

FLOW OF PROCESSING FOR CONVERTING REFERENCE  
DOCUMENT TO DOCUMENT CONFORMING TO COUNTRY  
TO WHICH APPLICATION IS MADE

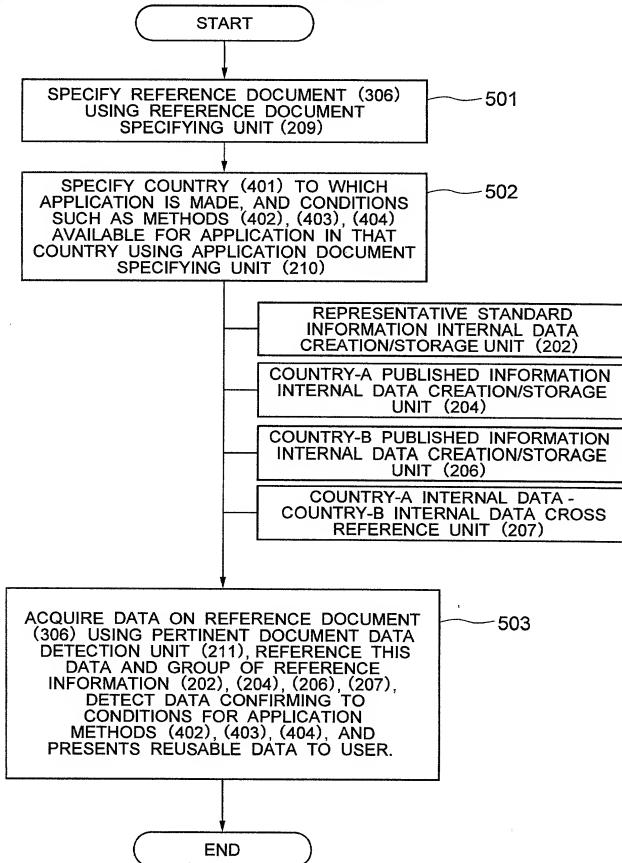


FIG. 6

EXAMPLE OF SCREEN WHEN AUTOMATIC  
CONVERSION IS INSTRUCTED


601

SCREEN FOR AUTOMATIC CONVERSION TO  
APPLICATION IN COUNTRY B

☒ AUTOMATICALLY CONVERT APPLICATION 1

AUTOMATIC TRANSLATION  
(LANGUAGE IN COUNTRY A →  
LANGUAGE IN COUNTRY B)  
PROCESSING

FORMAT CONVERSION  
PROCESSING



CONVERSION PROCESSING COMPLETED.  
DO YOU WANT TO REGISTER APPLICATION  
AS IT IS OR EDIT CONTENTS BEFORE  
REGISTRATION ?

604

REGISTER

605

EDIT

10076554-021902

FIG. 7

EXAMPLE OF POST-PREPARATION  
CONFIRMATION SCREEN

701

## APPLICATION PROCESSING CONFIRMATION SCREEN

DOCUMENTS APPLIED TO COUNTRY B HAVE BEEN PREPARED.  
DO YOU WANT TO CONFIRM EXAMINATION CONTENTS ?

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> APPLICATION 1 | <input type="checkbox"/> APPLICATION 2 | <input type="checkbox"/> APPLICATION 3 |
| <input type="checkbox"/> APPLICATION 4 | <input type="checkbox"/> APPLICATION 5 | <input type="checkbox"/> APPLICATION 6 |
| <input type="checkbox"/> APPLICATION 7 | <input type="checkbox"/> APPLICATION 8 | <input type="checkbox"/> APPLICATION 9 |

702

CONFIRM

PRESERVE

703



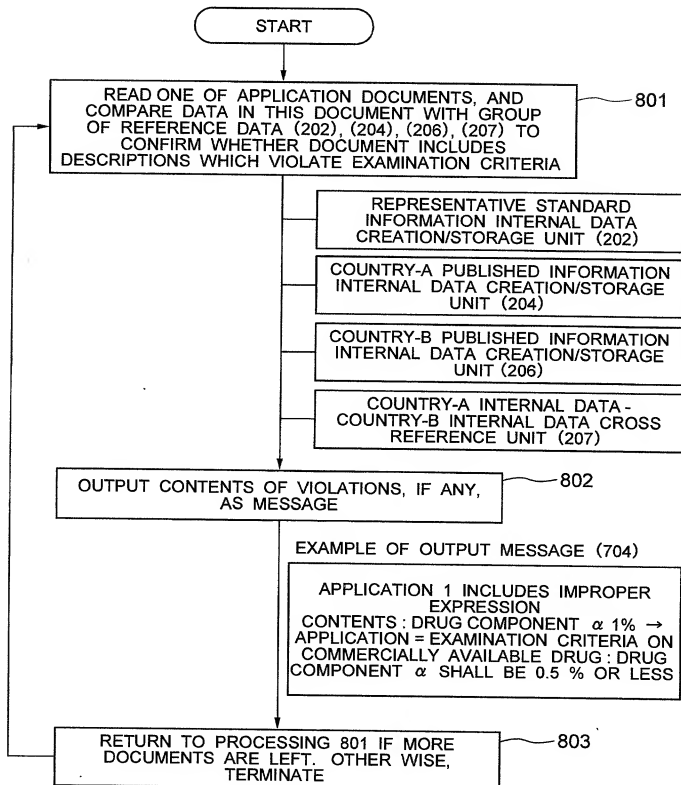
704

APPLICATION 1 INCLUDES IMPROPER EXPRESSION  
CONTENTS: DRUG COMPONENT  $\alpha$  1%  $\rightarrow$   
APPLICATION = EXAMINATION CRITERIA ON  
COMMERCIALLY AVAILABLE DRUG:  
DRUG COMPONENT  $\alpha$  SHALL BE 0.5% OR LESS

CHANGE DESCRIBED CONTENTS TO  
COMPLY DATA TO EXAMINATION  
CRITERIA.

705

## FIG. 8

PROCESSING FLOW OF EXAMINATION  
CONTENT CONFIRMATION UNIT (215)



9/11

# FIG. 9

EXAMPLE OF DATA MATCHING SCREEN

901

DATA MATCHING SCREEN

APPLICATION 1 INCLUDES IMPROPER EXPRESSION  
 CONTENTS : DRUG COMPONENT  $\alpha$  1%  $\rightarrow$  EXAMINATION  
 CRITERIA : DRUG COMPONENT  $\alpha$  SHALL BE 0.5 % OR LESS

903

FOR CHANGING  
COMPONENT, ASSOCIATED  
DATA = <CLINICAL DATA>  
MUST BE CHANGED.  
DO YOU WANT TO  
CHANGE ?

CHANGE

↓

904

SELECT ASSOCIATED DATA  
FOR REPLACEMENT

DRUG COMPONENT  $\alpha$  1 %

DRUG COMPONENT  $\alpha$  0.8 %

✓ DRUG COMPONENT  $\alpha$  0.5 %

DRUG COMPONENT  $\alpha$  0.1 %

DRUG COMPONENT  $\alpha$  0.08 mg

REPLACE

704

<APPLICATION 1>  
 <COMPONENTS>  
DRUG COMPONENT  $\alpha$  1 % ;  
 $\beta$ -CISTRON 0.025 % ;  
 DRUG COMPONENT  $\gamma$  0.08 mg  
 </COMPONENT>  
 <EFFECT>  
 ANTIPHLOGISTIC ACTION ON  
 INNER WALLS OF STOMACH AND  
 INTESTINE </EFFECT>  
 <DOSAGE>  
 ADULTS (15 YEAR-OLD OR MORE) :  
 TAKE ONE CAPSULE AFTER EVERY  
 MEAL, CHILDREN (15-YEAR-OLD OR  
 LESS) TAKE ONE CAPSULE A DAY  
 </DOSAGE>  
 <SIDE EFFECT>  
 LOSS OF APPETITE </SIDE EFFECT>  
 <CLINICAL DATA>  
 DATA ID - XXIIILLLL  
 COMPONENT : DRUG COMPONENT  $\alpha$   
 1 % ;  $\beta$ -CISTRON 0.025 % ; DRUG  
 COMPONENT  $\gamma$  0.08 mg  
 :  
 </CLINICAL DATA>  
 </APPLICATION 1>

902

905

PRESERVE APPLICATION 1  
AFTER REPLACEMENT

906

CANCEL

10076554-021902

## FIG. 10

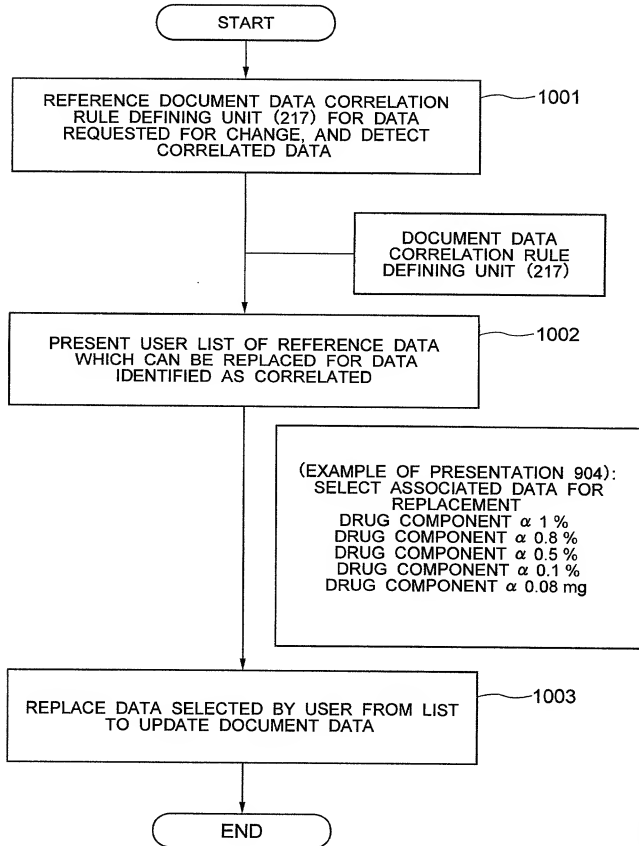
PROCESSING FLOW IN DOCUMENT  
MATCHING UNIT (216)

FIG. 11

EXAMPLE OF APPLICATION  
SUBMISSION SCREEN

1101

## APPLICATION SUBMISSION SCREEN

EXAMINATION CONTENTS HAVE BEEN CONFIRMED FOR ALL  
DOCUMENTS. DO YOU WANT TO SUBMIT DOCUMENTS TO  
INTENDED COUNTRY ?

- |  |  |  |
|--|--|--|
| <input type="checkbox"/> APPLICATION 1 | <input type="checkbox"/> APPLICATION 2 | <input type="checkbox"/> APPLICATION 3 |
| <input type="checkbox"/> APPLICATION 4 | <input type="checkbox"/> APPLICATION 5 | <input type="checkbox"/> APPLICATION 6 |
| <input type="checkbox"/> APPLICATION 7 | <input type="checkbox"/> APPLICATION 8 | <input type="checkbox"/> APPLICATION 9 |

SUBMIT

CANCEL



1102

SUBMISSION PROCESSING REQUEST HAS BEEN TRANSMITTED.

REQUEST TIME : XX:YY:ZZ IN STANDARD TIME OF COUNTRY B

(INTERNATIONAL STANDARD TIME = Date)

SUBMITTED DOCUMENTS AND SUBMISSION INFORMATION ARE  
PRESERVED BEFORE TERMINATION

STORAGE FILE : DOCUMENT ID = XXXIILLLLKKKK

PRODUCT NAME : GASTROINTESTINAL DRUG α